

Complete Summary

GUIDELINE TITLE

Smoking cessation.

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Smoking cessation. Ann Arbor (MI):
University of Michigan Health System; 2006 Aug. 12 p. [1 reference]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Smoking cessation. Guidelines for clinical care. Ann Arbor (MI): University of Michigan Health System; 2001 Feb. 9 p.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Tobacco dependence

GUIDELINE CATEGORY

Counseling
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Pediatrics

INTENDED USERS

Health Care Providers
Physicians

GUIDELINE OBJECTIVE(S)

To provide a systematic framework for care providers to assist patients in smoking cessation

TARGET POPULATION

Adult and adolescent smokers

INTERVENTIONS AND PRACTICES CONSIDERED

Screening

1. Assessment and documentation of smoking status
2. Assessment of readiness to quit

Treatment

1. Advice and counseling:
 - Brief clinic intervention model known as "3-A's and Refer" model: Ask, Advise, Assess, and Refer
 - Motivational intervention using "5 R's": Relevance, Risks, Rewards, Roadblocks, Repetition
2. Pharmacotherapy: First-Line:
 - Nicotine lozenge, such as Commit Lozenge
 - Transdermal nicotine patch, such as Nicoderm CQ, Nicotrol, or other generic nicotine transdermal patches
 - Nicotine gum (polacrilex), such as Nicorette, generic nicotine polacrilex
 - Nicotine nasal spray, such as Nicotrol NS
 - Nicotine inhaler, such as Nicotrol inhaler
 - Bupropion hydrochloride SR (Zyban®) or generic bupropion hydrochloride
 - Varenicline (Chantix®)
3. Pharmacotherapy: Second-Line:
 - Clonidine
 - Nortriptyline
4. Advice on weight gain after smoking cessation
5. Follow-up to prevent relapse

MAJOR OUTCOMES CONSIDERED

Efficacy of treatment as evidenced by smoking cessation rates

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The update of literature beyond the search performed for the initial University of Michigan Health System (UMHS) Smoking Cessation Guideline began with a literature search performed to produce "Treating Tobacco Use and Dependence. A Clinical Practice Guideline," US Public Health Service, 2000 June. The guideline team updated the Public Health Service literature search through a Medline search of literature January 1999 – April 2005. This search used the major keywords of: smoking [prevention & control], smoking cessation, tobacco use [prevention & control, rehabilitation]. The search was restricted to literature that was also referenced as either guidelines or controlled trials, as studies of humans, and as published in English. Specific searches were performed for the topics: counseling (includes assessment); pharmacologic treatment; other therapies (including complementary/alternative); pregnancy; adolescents; older adults; prevention (includes physician interactions with children and adolescents, counseling about having a smoke free home, and avoiding environmental tobacco smoke); and other smoking cessation guidelines, reviews of trials, or trials not included above.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of evidence that reflect the best available literature in support of an intervention or test:

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Observational trials
- D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Conclusions were based on prospective randomized clinical trials (RCTs) if available, to the exclusion of other data. If RCTs were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

University of Michigan Health System (UMHS) guidelines are reviewed in clinical conferences of physicians in departments to which the content is most relevant and by leadership in those departments. This guideline was reviewed by members of the following clinical units: Family Medicine, General Medicine, and General Pediatrics. Guidelines are approved by the Executive Committee on Clinical Affairs (ECCA).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the full text for additional information, including detailed information on dosing, duration, and instructions for nicotine replacement therapies, bupropion, and varenicline and cost of drugs, counseling and motivational interventions, and considerations for special populations (i.e., pregnant and breastfeeding patients, racial and ethnic minorities, patients with psychiatric co-factors, non-cigarette tobacco users, gender concerns, older smokers, and hospitalized smokers).

The levels of evidence [A-D] are defined at the end of the Major Recommendations.

- ASK all patients about smoking status and assess smoker's readiness to quit. Smoking status should be documented in the medical record.
- ADVISE all smokers to seriously consider making a quit attempt using a clear and personalized message. Advice as brief as 3 minutes is effective [A].
- ASSESS all smokers' willingness to make a quit attempt. If not yet ready to quit, offer motivational intervention using 5 "R's" – relevance, risks, rewards, roadblocks, repetition.
- REFER patients interested in quitting within 30 days to a tobacco treatment specialist or other appropriate tobacco cessation program. Alternatively, health care providers can directly provide the following treatment:

Treatment Options

- ASSIST those ready to make a quit attempt:
 - Set a quit date. Quit date abstinence is a strong predictor of long-term success [C].
 - Give advice on quitting and provide supplementary materials.
 - Prescribe pharmacologic therapy as appropriate. Nicotine replacement therapies, bupropion hydrochloride, and varenicline have been proven effective [A].
- ARRANGE follow-up either with phone call or office visit.
 - Prevent relapse by congratulating successes and reinforcing reasons for quitting.
 - Assess any difficulties with pharmacologic therapy.

Definitions:

Levels of Evidence

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Observational trials
- D. Opinion of expert panel

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document titled, "Clinician's Actions to Help Patients Quit Smoking."

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (see "Major Recommendations").

Conclusions were based on prospective randomized clinical trials if available, to the exclusion of other data; if randomized controlled trials were not available,

observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Effective interventions and strategies for health care providers to assist patients in smoking cessation

POTENTIAL HARMS

Side Effects of Medications

- Nicotine Lozenge - Headache, diarrhea, flatulence, heartburn, hiccups, nausea, coughing, sore throat, and upper respiratory infection (occurring in > 5% of patients)
- Transdermal nicotine patch - Skin reactions such as pruritus, edema, rash; sleep disturbance
- Nicotine gum (polacrilex) - Jaw fatigue, hiccups, belching, and nausea
- Nicotine nasal spray - Nasal irritation/rhinorrhea (98% of patients), sneeze, cough.
- Nicotine inhaler - Cough, mouth and throat irritation
- Bupropion hydrochloride SR (Zyban®) and bupropion hydrochloride - Insomnia and dry mouth. It should be used with caution in patients with predisposition to seizure (i.e., head trauma, alcohol withdrawal, concomitant use with other medications that lower seizure threshold – antipsychotics, antidepressants, theophylline)
- Varenicline (Chantix ®) - Nausea, insomnia, and unusual dreams; should not be used in conjunction with nicotine replacement therapy (NRT) products
- Clonidine - Dry mouth and sedation
- Nortriptyline - Dry mouth

Few studies have addressed the safety of nicotine replacement therapy or bupropion in pregnancy directly; however, studies show that less nicotine and fewer metabolites cross the placenta with the use of nicotine replacement therapy than with smoking itself. The U.S. Food and Drug Administration (FDA) pregnancy risk categories are: bupropion – category B, nicotine transdermal, spray and inhaler – category D, nicotine gum – category C, varenicline – category C.

Most smokers who quit will gain weight, but the majority will gain less than 10 pounds.

CONTRAINDICATIONS

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Bupropion hydrochloride and Bupropion hydrochloride SR (Zyban®) are contraindicated in patients with seizure disorder, major head trauma, eating disorders, and in patients on Wellbutrin® or monoamine oxidase (MAO) inhibitors.

QUALIFYING STATEMENTS

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These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Organizing a Health Care Site to Support Smoking Cessation Efforts

Successful intervention programs require coordinated efforts at a health care site. Several clinic personnel may be involved in operational steps of "Asking, Advising, Assessing, and Referring". Clinicians should help their clinics develop a coordinated plan of tasks and who will perform them. Some specific areas for planning include:

Record smoking status. Institute an office system to identify all smokers:

- Identify where smoking status will be recorded. Options include making smoking status part of vital signs, placing smoking status stickers on charts, or including smoking status on a section of the Problem Summary List.
- Determine who will routinely ask and record the information.
- Instruct staff regarding their roles in documentation.
- Reinforce the value of the documentation.

Smoking cessation follow-up. Develop a system and assigned role(s) at the health care site to:

- Ensure the availability of patient education materials on smoking cessation.
- Establish procedures for clinicians to provide a designated follow-up person with information on patients who are setting quit dates. Coordinate follow-up phone calls in conjunction with quit dates.
- Provide follow-up cessation counseling as needed at subsequent clinic visits.
- Refer patients to more intensive counseling programs for smoking cessation, as needed.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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University of Michigan Health System; 2006 Aug. 12 p. [1 reference]

ADAPTATION

The guideline was adapted from the Public Health Service guideline: Treating tobacco use and dependence. A clinical practice guideline. Rockville (MD): U.S. Department of Health and Human Services, Public Health Service; 2000 Jun. Clinical Practice Guideline.

DATE RELEASED

1998 Sep (revised 2006 Aug)

GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

SOURCE(S) OF FUNDING

University of Michigan Health System

GUIDELINE COMMITTEE

Smoking Cessation Guideline Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Team Leader: John G Frohna, MD, MPH, Internal Medicine and Pediatrics

Team Members: R Van Harrison, PhD, Medical Education; David C Serlin, MD, Family Medicine; Linda A Thomas, MS LLP, UMHS Tobacco Consultation Service

Guidelines Oversight Team: Connie Standiford, MD; William E Chavey, MD; R Van Harrison, PhD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

None of the members of the Smoking Cessation Guideline Team have relationships with commercial companies whose products are discussed in this guideline. (The members of the team are listed on the front page of the original guideline.)

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Smoking cessation. Guidelines for clinical care. Ann Arbor (MI): University of Michigan Health System; 2001 Feb. 9 p.

GUIDELINE AVAILABILITY

Electronic copies: Available for download in Portable Document Format (PDF) from the [University of Michigan Health System Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

Continuing Medical Education (CME) information is available from the [University of Michigan Health System Web site](#).

PATIENT RESOURCES

The following are available:

- How to quit smoking. University of Michigan Health System; 2005 Oct. Various p. Available from the [University of Michigan Health System Web site](#).
- How to use your nicotine replacement product. University of Michigan Health System; 2005 Oct. Various p. Available from the [University of Michigan Health System Web site](#).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on January 11, 2002. The information was verified by the guideline developer as of February 8, 2002. This summary was updated by ECRI on November 10, 2006. The updated information was verified by the guideline developer on December 12, 2006.

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